EXHIBIT 8

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

VITAL CONNECT, INC.,
Petitioner,

v.

BARDY DIAGNOSTICS, INC.,
Patent Owner.

IPR2023-00381
Patent 11,051,743

PATENT OWNER'S PRELIMINARY RESPONSE

TABLE OF CONTENTS

EXHIBIT LIST

Exhibit No.	Document
2001	Declaration of Dr. Per Reinhall, Ph.D.
2002	Curriculum Vitae of Dr. Per Reinhall, Ph.D.
2003	Statutory Disclaimer regarding U.S. Patent No. 11,051,743
2004	U.S. Patent No. 8,116,841
2005	U.S. Pub. No. 2015/0023873
2006	U.S. Patent No. D639,437
2007	U.S. Patent No. 8,285,370

Patent Owner Bardy Diagnostics, Inc. ("Patent Owner") submits the following patent owner preliminary response pursuant to 37 C.F.R. § 42.107 in response to the petition for *inter partes* review ("Petition") filed by Vital Connect, Inc. ("Petitioner") concerning Patent No. 11,051,743 ("the '743 Patent").

I. INTRODUCTION

Petitioner has failed to meet its burden for at least three reasons, so the Board can and should deny institution. ***First***, both of Petitioner's grounds for unpatentability rely on prior art that is the same, or substantially the same, as art considered during the prosecution of the '743 Patent. Petitioner simply ignores this fact and does not explain—as it must under the Board's precedential decision in *Advanced Bionics*—why the Office committed a material error when previously considering this art. Petitioner not only fails to address the issue, it makes an incorrect (or at least incomplete) statement that "[n]one of the references on which these grounds are based was applied by the Examiner during prosecution of the '743 patent."

Petitioner's failure to justify its use of substantially similar art is inexcusable. Almost a half year before the Petition was filed, Patent Owner informed Petitioner that Petitioner's primary asserted art was cumulative of the earlier art, so Petitioner was aware of the issue, but chose not to address it in the Petition. Consequently, the Board should exercise its discretion under 35 U.S.C. § 325(d) and deny institution

of the Petition given (i) the substantial similarity between the art asserted in the Petition and previously considered art and (ii) Petitioner's failure to show material error by the Office under the prior consideration.

Second, Petitioner provides no explanation or support for its overly broad definition of a person or ordinary skill in the art that encompasses non-engineers who have no experience designing devices. Petitioner merely asserts its definition. Providing evidence in support of the level of ordinary skill in the art was mandatory here because the Petition brings only obviousness grounds, which must be assessed through the lens of the proper artisan. Yet, the Petition does what the Board has repeatedly warned against: it relies on nothing more than conclusory statements and attorney arguments on key factual issues. Because Petitioner lacks evidence on a key factual issue underlying its obviousness grounds, Petitioner is not likely to prevail with respect to any challenged claim, so the Board should deny institution under 35 U.S.C. § 314(a).

Third, Petitioner's definition of a person of ordinary skill in the art is not merely unsupported, it is wrong. Under the correct definition, there is (among other problems) a total lack of evidence on essential aspects of Petitioner's asserted unpatentability grounds. In particular, Petitioner only asserts obviousness theories, so it needs credible evidence that a person of ordinary skill would have had reasons to combine the cited art.

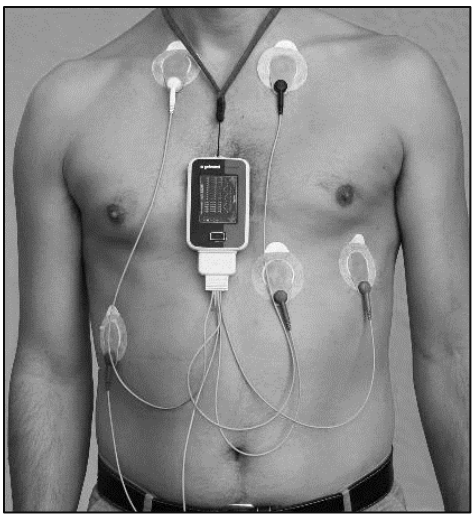
It attempts to provide that evidence via the declaration of Dr. Joseph Akar, but he is incapable of providing credible testimony because he is not, and never was, a person of ordinary skill in the art. Dr. Akar is a physician who lacks an engineering education (or equivalent knowledge) and has never designed a medical device, let alone a device in the field of the '743 Patent. Petitioner has no other evidence showing why a person of ordinary skill would modify the cited references, leading to an outright failure of proof. Consequently, the Board should deny institution under 35 U.S.C. § 314(a) because Petitioner has not, and cannot, show a reasonable likelihood of establishing unpatentability on any challenged claim.

II. THE CHALLENGED PATENT

The '743 Patent, titled "Electrocardiographic Patch," claims inventions in the general field of electrocardiographic monitoring and the particular field of electrocardiography patches. (Ex. 1001 at 1:21–23.) An electrocardiogram ("ECG") reports the electrical signals of a patient's heart and is used by physicians to diagnose heart problems. (*See id*. at 1:27–49.) Conventionally, ECGs are generated by ECG machines connected to 12 electrical leads that are placed in "well-established traditional chest locations." (*See id*. at 1:31–38.) Depending on the application, ECGs may be recorded over a wide variety of time periods, potentially for just a few minutes or up to 30 days. (*See id*. at 1:49–52, 1:60–2:2.) Long-term ECG monitoring can provide a variety of benefits relative to short-term monitoring, but the design of

ECG monitoring devices—which can be "arduous to employ, cumbersome to the patient, and excessively costly"—can prevent successful long-term monitoring. (*See id*. at 1:60–2:8.)

Holter monitors are the conventional solution for outside-the-clinic, portable ECG monitoring, although their design typically limits their use to 48 hours in practice. (*See id*. at 2:36–41; *see also id*. at 2:51–53.) The following shows a representative Holter monitor on a patient:



(Ex. 2001 ¶ 53 (citing https://commons.wikimedia.org/wiki/File:Alex_CM4000.jpg).) The '743 Patent also explains that "wearable stick-on monitoring devices" had been developed and commercialized into two products sold under the ZIO brand. (Ex. 1001 at 2:58–62.) Depending on the product, these devices could be worn for up to 14 or 30 days. (*Id*. at 2:63–67.)

The '743 Patent identified several deficiencies in these products and noted that there "remains a need for an extended wear continuously recording ECG

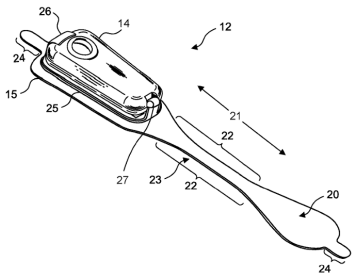
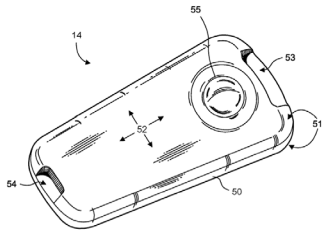
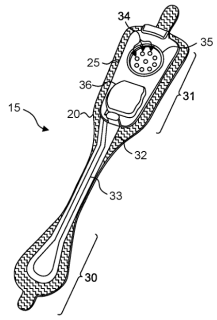
monitor practicably capable of being worn for a long period of time in both men and women and capable of recording atrial signals reliably." (*Id*. at 3:36–39.) It identified the need for a device with mechanical and electrical design innovations that could overcome the following problems:

- Maintaining the electrodes in a position to receive high-quality ECG signals despite the "various compressional, tensile, and torsional forces" imparted on the device, including from patient movements.
- Allowing for sufficient adhesion of the device to support the full weight of the device, but still allowing removal or relocation of the device during the monitoring period, and without causing skin irritation.
- Allowing the patient to take baths or engage in other activities that could damage the electronics.
- Enabling placement of the electrodes in the best location for a given patient, even if anatomy (i.e., breasts or pectorals) would otherwise make that placement challenging.
- Having sufficient battery power and sufficient memory to enable detailed, long-term monitoring without undermining the goals above.

(*See id.* at 2:11–3:18.)

The '743 Patent describes an advancement in wearable-monitor technology that meets the above challenges via a two-part design. The "monitor" (the overall

device) consists of a "patch" portion and a "recorder" portion. (Ex. 1001 at 5:44–47, Figs. 4–6.)

Monitor (Patch with Recorder)	
Recorder	
Patch	

(*Id*. at Figs. 4–6; 5:15–21.)

The inventions of the '743 Patent move the battery away from the memory that the battery powers (namely, away from the recorder hardware), a design that solves challenges concerning the various compressional, tensile, and torsional forces on the device; vulnerability of electronics; and sufficient battery life. (*See* Ex. 1001 at 12:58–13:19.) For example, this placement "lowers the center of gravity of the overall wearable monitor 12 and thereby helps to minimize shear forces and the effects of movements of the patient and clothing." (*Id*. at 12:62–66.) This also allows

for the use of an adhesive that is both a hydrocolloid and applied to only a portion of the monitor's patient-contacting surface, which results in a design that is non-irritating to the skin while allowing the device to flex in response to compressional and torsional forces. (*Id*. at 10:34–42.)

III. THE PETITION

The Petition argues two grounds for unpatentability, namely that the claims of the '743 Patent are obvious in light of (i) the combination of International Pub. No. WO 2010/104,952 ("*Mazar*") and Patent No. 11,116,447 ("*Yang*") and (ii) the combination of Patent App. Pub. No. 2011/0077497 ("*Oster*") and *Yang*. (*See* Petition at 5.)

Although Petitioner challenges Claims 1–20 of the '743 Patent, only Claims 11–20 are relevant to the Board's consideration of the Petition because Patent Owner statutorily disclaimed Claims 1–10 (Ex. 2003). "The patent owner may file a statutory disclaimer" and "[n]o *inter partes* review will be instituted based on disclaimed claims." 37 CFR § 42.107.

Petitioner asserts that "[n]one of the references on which these grounds are based was applied by the Examiner during prosecution of the '743 patent." (Petition at 5.) This quote appears to be crafted to avoid admitting that, during prosecution of the '743 Patent, the Office considered *Oster*, considered *Yang*'s parent application (with nearly identical disclosures to *Yang*), and considered another patent by

inventor Mazar (with substantively the same disclosures as *Mazar*). (*See* Petition at 5.) The Petition does not address why the Board should evaluate either of the Petition's grounds given that the Office has already considered art that is the same, or substantially the same, as the art relied upon in the Petition. (*See id*.)

The Petition exclusively brings obviousness grounds, so Petitioner raises—as it must—several purported reasons why a person of ordinary skill in the art would have modified *Mazar* and/or *Oster* in view of the disclosures of *Yang*. (*See, e.g.,* Petition at 5, 26–29.) To support its conclusions that a person of ordinary skill would have such reasons to combine, Petitioner relies exclusively on the testimony of Dr. Joseph Akar. (*E.g., id*. at 26–29; Ex. 1002 ¶¶ 91–104.)

Dr. Akar is a physician who teaches at a college of medicine, lacks engineering education (or equivalent work experience), and has never designed any medical devices, including devices in the field of cardiac monitoring. (Ex. 1002 ¶¶ 5–7, 22.) Petitioner apparently justifies its reliance on Dr. Akar's testimony by asserting that a person with no experience designing medical devices and no engineering education qualifies as a person of ordinary skill in the field of the '743 Patent. (Petition at 5–6.) Neither Petitioner nor Dr. Akar provides any explanation or evidence in support of their conclusory definition of a person of ordinary skill. (*See id*.; Ex. 1002 ¶ 43.)

IV. INSTITUTION SHOULD BE DENIED BECAUSE PETITIONER RELIES ON PREVIOUSLY CONSIDERED ART WITHOUT SHOWING A MATERIAL ERROR

The Board should deny institution under 35 U.S.C. § 325(d) because the Petition is devoid of any evidence justifying Petitioner's implicit request that the Board reconsider prior art disclosures that were previously considered by the Office.

Under 35 U.S.C. § 325(d), the Board may deny institution of a proceeding if the petitioner challenges the patent on matters previously presented to the Office. *Advanced Bionics, LLC v. Med-EL Elektromedizinische Gerate GMBH*, IPR2019–01469, 2020 WL 740292, at *2 (PTAB Feb. 13, 2020) (precedential). Denial is proper if (1) the petitioner presents the same, or substantially the same, prior art or arguments previously presented to the Office, and (2) the petitioner fails to demonstrate that the Office erred in a manner material to the patentability of the challenged claims. *See id.* at *2. Under this framework, the Board may look to the non-exclusive list of factors listed in *Becton, Dickinson and Co. v. B. Braun Melsungen AG*, IPR2017–01586, 2017 WL 6405100 (PTAB Dec. 15, 2017) (precedential in part) ("*BD* Factors") to determine whether the *Advanced Bionics* test is satisfied. *See Advanced Bionics*, 2020 WL 740292 at *4, *4 n.10. If the test is met, the Board will exercise its discretion not to institute, which embodies the commitment to defer to "previous Office evaluations of the evidence of record unless material error is shown." *Id.* at *3.

As explained further below, even though Petitioner had the burden of establishing that the Office materially erred when examining the '743 Patent, the Petition is completely silent on the § 325(d) issue. (*See generally* Petition.) Indeed, Petitioner does not identify any error (much less a material error) during the examination of the '743 Patent, even though (i) the Petition relies on *Mazar*, *Yang*, and *Oster* as the basis for its unpatentability grounds and (ii) the Office considered the same, or substantially similar, art as those references during the '743 Patent's prosecution history. (*See generally id.)* Petitioner's omission is particularly troubling given that Patent Owner informed Petitioner that the Office had granted the '743 Patent despite considering substantially similar prior art to Petitioner's primary reference. (*See* Ex. 1018 at 2.)

A. Petitioner Relies on Identical, or Substantially Similar, Art as the Office Considered During Examination.

1. Relevant legal principles.

Under the first prong of the *Advanced Bionics* framework, the Board determines whether the prior art (or arguments) are the same or substantially the same by considering the similarities and material differences between the asserted art and the prior art involved during examination. *Advanced Bionics*, 2020 WL 740292, at *4, *4 n.10. In doing so, the Board may consider the cumulative nature of the art asserted in the petition and the prior art evaluated during examination, the

extent of the overlap between arguments made during examination, and the manner in which the petitioner relies on the prior art (*BD* Factors a, b, and d). *Id*.

Previously presented prior art includes art made of record by the examiner, and art provided to the Office by an applicant, such as on an Information Disclosure Statement ("IDS"). *Id.* at *3. However, if the asserted art is not the same as previously presented art, then the Board evaluates whether the asserted art "discloses substantially the same information," such that it is substantially the same as previously presented prior art. *See id.* at *6–7.

Further, the Board considers intrinsic evidence (such as a certification from the examiner) to determine if, and to what extent, the Office has already reviewed and considered the prior art. *See Nespresso USA, Inc. v. K-Fee Sys. GmBH*, IPR2021–01223, 2022 WL 214445, at * 6 (PTAB Jan. 18, 2022). For instance, in *Nespresso*, the Board found that the examiner considered the references in the IDS because the examiner marked the IDS with the statement "considered except where lined through," certified this statement with their initials, and none of the references were "lined through." *Id.* at *6; *see also* M.P.E.P. § 609.05(b) (instructing examiners to indicate whether information on an IDS has been considered by stamping each page with the phrase "All references considered except where lined through" and then lining through only those references *not* considered).

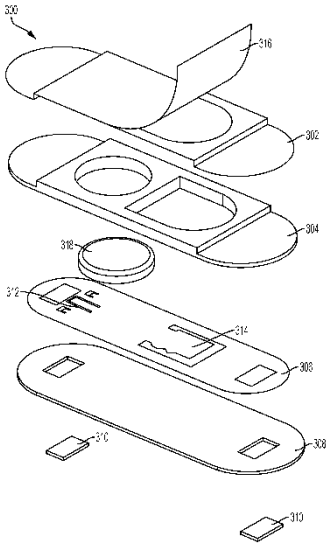
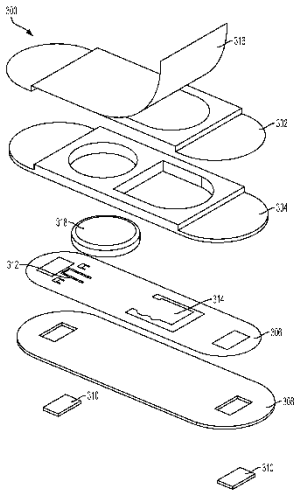
2. *Oster*, *Yang*'s nearly identical parent, and *Mazar*'s substantive equivalent were all considered previously.

Oster, *Yang*, and *Mazar*—the references asserted in one or both of the Petition's two asserted grounds of unpatentability—are the same, or the same for all material purposes, as art previously considered by the Office, and the disclosures relied upon by Petitioner are all substantively the same as disclosures in the previously presented art.

Oster was presented to the Office via an IDS and considered by the examiner. (*See* Ex. 1007 at 87:114.) Notably, the examiner certified that all references listed in the IDS were considered "except where lined through," and *Oster* was not lined through. (*Id.*) Therefore, Oster was previously reviewed and considered by the Office. *See Nespresso*, 2022 WL 214445, at * 6; M.P.E.P. § 609.05(b).

Yang itself was not before the Office during examination of the '743 Patent, but *Yang* is a continuation of US Patent No. 9,277,864 ("*Yang Parent*") (Ex. 1019), which was presented to the Office via an IDS and considered by the examiner. (*See* Ex. 1005 at Related U.S. Application Data; Ex. 1007 at 39:13.) Practically by definition, parent and child patents are substantially the same because the patents have nearly identical specifications and the exact same figures. *See Google LLC v. Kewazinga Corp.*, IPR2021–00527, 2021 WL 3746361, at *6 (PTAB Aug. 24, 2021); *see also* M.P.E.P. § 201.7 ("The disclosure presented in the continuation must not include any subject matter which would constitute new matter . . . ."). Indeed,

Yang and the *Yang Parent* have a nearly identical specification and the figures in both patents are identical. (*Compare* Ex. 1005 Specification and Figures *with* Ex. 1019 Specification and Figures). For example, and for the avoidance of doubt, the following comparison of *Yang* material cited by Petitioner with corresponding *Yang Parent* disclosures are representative of the references' sameness:

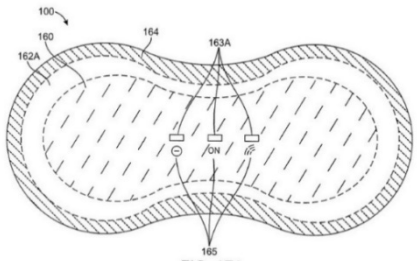
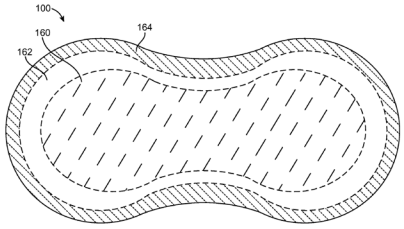
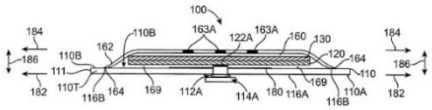
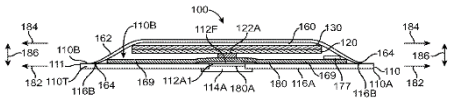
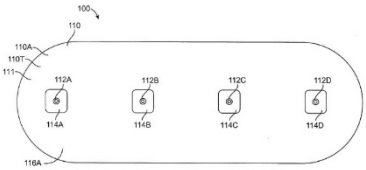
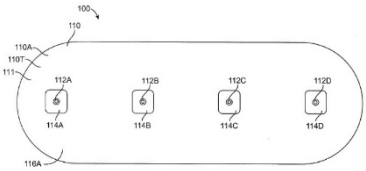
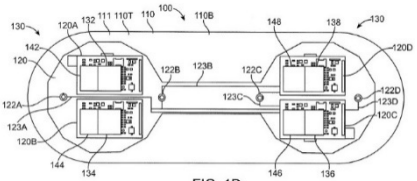
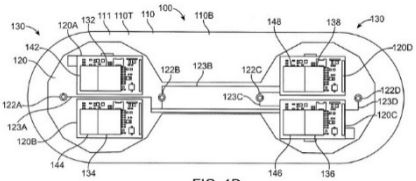
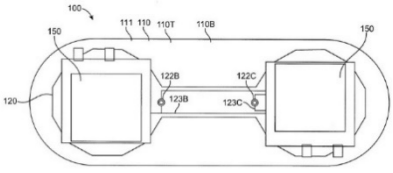
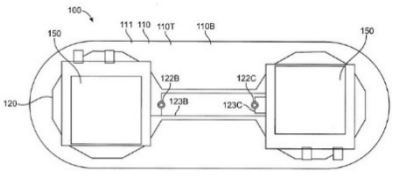
Yang	***Yang Parent Considered by Examiner***
Ex. 1005 at 2:24–50	Ex. 1019 at 2:16–43
Ex. 1005 at 3:2–4, 63–4:2	Ex. 1019 at 2:62–64, 3:57–63
Ex. 1005 at 4:2–4	Ex. 1019 at 3:63–65
Ex. 1005 at 4:39–42	Ex. 1019 at 4:32–35
Ex. 1005 at 2:48–55	Ex. 1019 at 2:41–48
Ex. 1005 at 4:28–38	Ex. 1019 at 4:21–31
Ex. 1005 at 5:41–53	Ex. 1019 at 5:33–45
Ex. 1005 at 4:67–5:4	Ex. 1019 at 4:59–4:63
Ex. 1005 at 5:23–31	Ex. 1019 at 5:15–23
 FIG. 3	 FIG. 3

Notably, as with *Oster*, the examiner also certified that all the references listed in the IDS were considered except where lined through, and the *Yang Parent* was not lined through. (*See* Petition Ex. 1007 at 39:13.) Therefore, *Yang* is substantially the same as, and cumulative with, the *Yang Parent*, which was previously reviewed and considered by the Office during examination. *See Nespresso*, 2022 WL 214445, at * 6.

Mazar was not presented to the Office during examination, but the Office reviewed and considered US Patent No. 8,116,841 ("*Mazar '841*") (Ex. 2004)—another patent with Scott Mazar as an inventor—that makes the same or substantially the same disclosures as *Mazar*. (*See* Petition Ex. 1007 at 73:85.) Importantly, the examiner certified that all the references listed in the IDS were considered except where lined through, and *Mazar '841* was not lined through. (*See id.*)[1]

[1] In fact, the Examiner reviewed and considered eight other patents and patent publications listing Scott Mazar as an inventor that make the same or substantially the same disclosures as *Mazar*, including: US Patent App. Publ. No. 2009/0076336, US Patent App. Publ. No. 2009/0076342, US Patent No. 8,591,430, US Patent App. Publ. No. 2014/0012154, US Patent No. 8,412,317, US Patent App. Publ. No. 2013/0085347, US Patent No. 8,795,174, and US Patent No. 8,285,356. (*See* Ex. 1007 at 53:64, 74:92, 96, 75:100, 76:109, 83:71, 73, 86:103.)

Mazar and *Mazar '841* are substantially the same for all purposes relevant to the Petition. This is clearly seen through a comparison of *Mazar* figures with the *Mazar '841* figures:

***Mazar* Figures (Ex. 1003)**	***Mazar '841* Figures (Ex. 2004)**
 FIG. 1F1	 FIG. 1F
 FIG. 1I1	 FIG. 1I1
 FIG. 1B	 FIG. 1B
 FIG. 1D	 FIG. 1D
 FIG. 1E	 FIG. 1E

The only differences between the two patents' figures relate to visual indicators and symbols (element 163A in *Mazar* Fig. 1F1, *see* Ex. 1003 ¶ 116), which are not relevant to the '743 Patent. (*See* Ex. 1001 at Claims.) Therefore, *Mazar* is substantially the same as *Mazar '841*. *See Advanced Bionics*, 2020 WL 740292, at *6–7 (holding the asserted art was substantially the same because it disclosed the same component shape and configuration); *see also Google*, 2021 WL 3746361, at *6 (finding the asserted art was substantially the same, in part, because it disclosed the same figures).

For the avoidance of doubt, *Mazar '841* provides the same or substantially the same disclosures as each of Petitioner's *Mazar* citations:

Petitioner's Proposed Element	***Mazar* Citation**	***Mazar '841* Citation**
Element 1-PRE: an electrocardiograph patch	Ex. 1003 ¶¶ 0002, 0098	Ex. 2004 at 1:53–60, 8:11–25
Element 1-A: a backing comprising an elongated strip with a mid-section connecting two ends of the backing	Ex. 1003 ¶¶ 0093, 0098	Ex. 2004 at 7:19–37, 8:11–25
Element 1-B: an electrocardiographic electrode on each end of the backing to capture electrocardiographic signals	Ex. 1003 ¶ 0098	Ex. 2004 at 8:11–25
Element 1-C: a flexible circuit comprising a pair of circuit traces electrically coupled to the	Ex. 1003 ¶ 0100	Ex. 2004 at 8:46–54

Petitioner's Proposed Element	***Mazar* Citation**	***Mazar '841* Citation**
electrocardiographic electrodes		
Element 1-D: a wireless transceiver to communicate at least a portion of the electrocardiographic signals	Ex. 1003 ¶¶ 0104–05	Ex. 2004 at 9:40–10:6
Element 11-E: a battery on one of the ends of the backing	Ex. 1003 ¶¶ 0031, 0033, 0064, 0094, 0113, 0145	Ex. 2004 at 5:15–16, 7:8–11, 34–51, 11:30–33, 19:22–35
Element 11-F: a processor powered by the battery	Ex. 1003 ¶ 0167	Ex. 2004 at 9:4–18, 40–52, 16:27–30
Element 11-G: memory electrically interfaced with the processor and operable to store samples of the electrocardiographic signals	Ex. 1003 ¶¶ 0048, 0095, 0104	Ex. 2004 at 7:53–65, 9:40–52
Claims 2 & 12: an accelerometer provided on the backing."	Ex. 1003 ¶¶ 0015, 0107	Ex. 2004 at 7:62–65, 10:14–26
Claims 3 & 13: a physiology sensor provided on the backing to measure body temperature	Ex. 1003 ¶¶ 0048, 0095	Ex. 2004 at 7:53–65
Claims 4 & 14: each of the ends of the backing is rounded on an outer edge	Ex. 1003 ¶ 0093	Ex. 2004 at 7:31–33
Claims 5 & 15: a physiology and activity sensor provided on the backing to measure one or more of heart rate,	Ex. 1003 ¶¶ 0013–14, 0048, 0095	Ex. 2004 at 7:53–65

Petitioner's Proposed Element	***Mazar* Citation**	***Mazar '841* Citation**
temperature, blood pressure, movement, sleep, footsteps, calories burned and estimated blood glucose level		
Claims 6 & 16: the electrocardiographic signals are converted to a different format and processed	Ex. 1003 ¶¶ 0013, 0104, 0197, 0199	Ex. 2004 at 9:40–52
Claims 7 & 17: the formatted electrocardiographic signals are retrieved by one of a server, a client computer and a mobile device via the wireless transceiver	Ex. 1003 ¶¶ 0013, 0091, 0104, 0197	Ex. 2004 at 6:26–7:4, 9:40–52
Claims 8 & 18: the electrodes are exposed on a contact surface of the backing	Ex. 1003 ¶¶ 0122, 0133	Ex. 2004 at 12:35–55, 16:44–52
Claims 9 & 19: a hydrocolloid adhesive provided on at least a portion of a contact surface of the backing	Ex. 1003 ¶0128	Ex. 2004 at 15:18–34
Claims 10 & 20: the hydrocolloid adhesive is provided on the ends of the backing, on the contact surface	Ex. 1003 ¶0128	Ex. 2004 at 15:18–34

Mazar is therefore substantially the same and cumulative of *Mazar '841*, which was previously reviewed and considered by the Office during examination of the '743 Patent.

As noted above, *Oster*, *Yang Parent*, and *Mazar '841* were all previously considered via the examiner's certification that he had considered them, which—given their similarity and substantial similarity to *Oster*, *Yang*, and *Mazar*—is wholly sufficient to satisfy the first prong of the *Advanced Bionics* test. *Advanced Bionics*, 2020 WL 740292, at *3. As numerous panels held after *Advanced Bionics*, there is no requirement for the previously considered art to have been the basis of rejection or other explicit, written analysis. *E.g.*, *Nespresso*, 2022 WL 214445, at *6; *Roku, Inc. v. Universal Elecs., Inc.*, IPR2019-01619, 2021 WL 2123912, at *3 (PTAB May 25, 2021); *Sony Interactive Entm't LLC v. Terminal Reality, Inc.*, IPR2020-00710, 2020 WL 6065186, at *5 (PTAB Oct. 13, 2020). Thus, the inclusion of *Oster*, *Yang Parent*, and *Mazar '841* on the lists of references certified as considered by the examiner is sufficient to the meet the first prong of *Advanced Bionics*.

B. Petitioner Failed to Offer Any Evidence that the Office Erred During Prosecution.

1. Relevant legal principles.

Under the second prong of the *Advanced Bionics* framework, a petitioner must demonstrate that the Office made a material error regarding examination to avoid discretionary denial. *See Advanced Bionics*, 2020 WL 740292, at *3. A threshold consideration is whether the petitioner sufficiently described how the examiner erred in its evaluation of the asserted prior art (*BD* Factor e). *Id.* at *4 n.10. As noted in

Section IV.A.2 above, the substantially similar art need not have been the subject of a rejection, so if the record of the Office's previous consideration is not well developed or silent, then a petitioner may show the Office erred by overlooking something persuasive (*see BD* Factors c, e, and f). *Id.* at 4. Examples of material errors include circumstances when an examiner overlooked specific teachings in the relevant prior art or if the examiner made an error of law (such as misconstruing a claim term) that impacted the patentability of the challenged claims. *Id*. at *3 n.9.

Where a petitioner fails to address the material-error requirement or otherwise is silent on the Section 325(d) inquiry, the petitioner fails to meet its burden, and the Board should deny institution. *See*, *e.g.*, *Wolfspeed, Inc. v. Trustees of Purdue Univ*., IPR2022–00761, 2022 WL 16823522, at *6 (PTAB Nov. 8, 2022); *Atrium Med. Corp. v. Bard Peripheral Vasulcar, Inc.*, IPR2021–01197, 2022 WL 128799, at *10 (PTAB Jan. 10, 2022); *Google*, 2021 WL 3746361, at *8–9 ; *Sony*, 2020 WL 6065186, at *5 . Indeed, *Atrium* explained that "[h]aving searched the Petition, we discern no express assertion that *any* error was committed by the Office," such that the "[p]etitioner leaves the Board to guess or develop its own theory on what error may have been committed. 2022 WL 128799, at *10. "[S]uch speculation [is] unwarranted." *Id.* Moreover, mere articulation of an unpatentability ground in the petition, without specific discussion of the supposed error in the prosecution history, does not satisfy *Advanced Bionics'* prong-two requirement that the petitioner

demonstrate a material error. *Advanced Bionics*, 2020 WL 740292, at *3 (petitioner does not establish a material error simply by disagreeing with the Office's conclusion regarding the prior art); *see also Roku*, 2021 WL 2123912, at *5.

2. Petitioner fails to address, let alone establish, a material error by the Office when it previously considered the art.

Petitioner plainly failed to establish a material error by the Office when it previously considered *Oster*, *Yang Parent*, and *Mazar '841*. Petitioner is completely silent on the issue, as it outright ignores the Section 325(d) issue. It chose to stay silent on the issue even though the Office's prior consideration of similar art had been raised by Patent Owner to Petitioner in correspondence many months before the Petition was filed. Because Petitioner failed to make any showing that the Office made a material error, its Petition should be denied. *See Advanced Bionics*, 2020 WL 740292, at *3 (explaining that if "the petitioner fails to make a showing of material error, the Director generally will exercise discretion not to institute *inter partes* review").

The Board has repeatedly denied institution when a petitioner fails to make any showing that the examiner materially erred during prosecution. *See e.g.*, *Microsoft Corp. v. Almondnet, Inc.*, IPR2022–01319, Paper 9 at 10–11 (PTAB Jan. 30, 2023) (denying institution because the petitioner did not make any substantive showing that the examiner erred); *Becton, Dickinson*, 2017 WL 6405100, at *8 (noting the petitioner did not point to any examiner error).

Here, Petitioner does not make any allegations that the examiner erred (much less materially erred) when considering the asserted art during examination of the '743 Patent. (*See generally* Petition.) Instead, Petitioner (wrongly) asserts that the '743 Patent is obvious in light of *Mazar* and *Yang*, or *Oster* and *Yang*, without explaining how the examiner made an error in ultimately arriving at the opposite conclusion. (*See generally id.*) By failing to articulate how the examiner erred when evaluating the asserted art, Petitioner is merely indicating that it disagrees with how the examiner treated the prior art and therefore falls short of establishing that institution is proper. *See Roku*, 2021 WL 2123912, at *5; *Advanced Bionics*, 2020 WL 740292, at *3.

For the avoidance of doubt, it is not enough for Petitioner to assert that the challenged patent is obvious in light of the prior art. *See Roku*, 2021 WL 2123912, at *5. Rather, a petitioner must adequately explain how any "alleged demonstration of obviousness" shows the examiner made an error material to the patentability of the claims. *Id.* Indeed, *Roku* found that it was within the Board's discretion to deny institution when the petitioner had ample opportunity to discuss the *BD* Factors, "but did not adequately address the analysis." *Id.*

Nor is it enough that Petitioner's unpatentability grounds cite the testimony of its expert Dr. Joseph Akar. Merely pointing to expert testimony without further analysis fails to establish that the examiner materially erred. *See Nespresso*, 2022

WL 214445, at *14 (merely stating an obviousness analysis supported by expert testimony without providing any further analysis is insufficient to show the Office materially erred); *see also Becton, Dickinson*, 2017 WL 6405100, at *9 (expert testimony was entitled to little or no weight because it failed to provide probative evidence). Regardless, as discussed in Section VI.B.1 below, Dr. Akar's testimony has no credible value.

Petitioner's omission is particularly glaring given that Patent Owner informed Petitioner that the patent examiner had considered substantially similar art to *Mazar*, and it provided this notice over half a year before Petitioner filed its Petition. (*See* Petition Ex. 1018 at 2.) As in *Roku*, Petitioner had ample opportunity to address the *Advanced Bionics* test, and it had prior warning that the asserted art was previously considered by the Office. (*See id.*) Indeed, not only did Petitioner ignore the issue, it made the misleading statement that "[n]one of the references on which [the asserted] grounds are based was applied by the Examiner during prosecution of the '743 patent." (Petition at 5.) Regardless, even though it was aware of the § 325(d) issue, Petitioner decided not to address it, leaving the Board to fill in the blanks of its arguments. (*See generally* Petition.)

Consequently, the Board should exercise its discretion under 35 U.S.C. § 325(d) and deny institution of the Petition given (i) the substantial similarity between the previously considered *Oster*, *Yang Parent*, and *Mazar '841* references

and the currently asserted *Oster*, *Yang*, and *Mazar* references and (ii) Petitioner's failure to show material error by the Office under the prior consideration, especially when Petitioner knew the issue was ripe.

V. INSTITUTION SHOULD BE DENIED BECAUSE PETITIONER FAILED TO SUPPORT ITS DEFINITION OF A PERSON OF ORDINARY SKILL

Institution should be denied under 35 U.S.C. § 314(a) because Petitioner fails to provide any evidence supporting its definition of a person of ordinary skill in the art ("POSITA"), which is a critical factual issue given that the Petition relies exclusively on obviousness grounds. As is explained in Section VI below, Petitioner's definition is substantively wrong, but the Board need not reach that issue, because Petitioner's evidentiary failure alone justifies non-institution.

The Board may not authorize institution of an *inter partes* review unless the petition shows that there is "a reasonable likelihood that the petitioner would prevail with respect to at least 1 of the claims challenged in the petition." 35 U.S.C. § 314(a). To prevail under an obviousness theory—the only grounds asserted in the Petition—Petitioner must demonstrate unpatentability under the *Graham* factors, which include (among other things) "the level of skill in the art." *Graham v. John Deere Co. of Kansas City*, 383 U.S. 1, 17–18 (1966). A Petition that relies on mere conclusions and attorney argument, rather than evidence, cannot demonstrate a

reasonable likelihood of prevailing. *See Xerox Corp. v. Bytemark, Inc.,* IPR2022-00624, 2022 WL 3648989, at *6 (PTAB Aug. 24, 2022) (precedential).

The Petition asserts that the relevant field is "electrocardiographic monitoring." (Petition at 8.) Petitioner and its expert, Dr. Joseph Akar, offer two alternate sets of POSITA qualifications: (i) an education requirement (a "bachelor's degree" in one of several medical disciplines or electrical engineering) with two to three years of "clinical experience in the field of biomedical engineering;" or (ii) several years of "medical work" with "knowledge of the electronic design and operation of cardiac monitoring technologies." (Petition at 5–6.) On their face, Petitioner's definitions are so broad that they would qualify a person as a POSITA in the field of electrocardiographic monitoring even if he or she was a non-engineer that lacks experience designing electrocardiographic monitors or any other type of medical device.

The Board is left guessing how Petitioner and Dr. Akar reached this conclusion, so the Board should deny institution. To determine the level of ordinary skill in the art, one may consider factors such as "(1) the educational level of the inventor; (2) type of problems encountered in the art; (3) prior art solutions to those problems; (4) rapidity with which innovations are made; (5) sophistication of the technology; and (6) educational level of active workers in the field." *Daiichi Sankyo Co. v. Apotex, Inc.*, 501 F.3d 1254, 1256 (Fed. Cir. 2007) (internal quotation marks

omitted). Yet neither Petitioner nor Dr. Akar discusses any of these factors or any other factors that may be relevant to the POSITA inquiry. (Petition at 5–6; Ex. 1002 ¶ 43.) Instead, Petitioner merely asserts its POSITA definition without any explanation, with only a citation to Dr. Akar's declaration for support. (Petition at 5–6.) Dr. Akar simply parrots the definition in the Petition and provides no explanation of how he reached this conclusion. (*Id.* ¶ 43.)

Because Petitioner and Dr. Akar provide no explanation or supporting evidence for their POSITA definition—they just assert it—the Board lacks evidence upon which the Board can accept Petitioner's definition. The Board must rely on evidence, not conclusory, unsupported statements. 37 C.F.R. § 42.65 ("Expert testimony that does not disclose the underlying facts or data on which the opinion is based is entitled to little or no weight."). Lacking any evidence supporting this required *Graham* factor, the Board should deny institution. *See TQ Delta, LLC v. CISCO Sys., Inc.*, 942 F.3d 1352, 1360–63 (Fed. Cir. 2019) (overruling Board obviousness determination because only conclusory expert statements supported what a POSITA would have done); *see also Xerox*, 2022 WL 3648989, at *6 (denying institution and holding that expert opinions that merely parrot allegations in the petition should be given little to no weight).

VI. INSTITUTION SHOULD BE DENIED BECAUSE PETITIONER'S EXPERT IS NOT COMPETENT TO OPINE ON KEY OBVIOUSNESS ISSUES, AND PETITIONER HAS NO OTHER RELEVANT EVIDENCE

Institution should be denied under 35 U.S.C. § 314(a) because the Petition asserts exclusively obviousness grounds to support institution, yet the Petition offers no credible evidence that a person of ordinary skill would have a reason to combine the prior art to create the inventions claimed by the '743 Patent. Petitioner's only reason-to-combine evidence comes from the testimony of Dr. Joseph Akar, but Dr. Akar is not (and never was) a person of ordinary skill in the relevant art, so his opinions are not credible. Lacking any other reason-to-combine evidence—for example, there is no teaching, suggestion, or motivation to combine in the prior art references themselves—the Petition's only grounds fail. Lacking credible evidence of reasons to combine, the Petition necessarily does not demonstrate a reasonable likelihood of success, so institution should be denied.

A. A Person of Ordinary Skill in the Art for the '743 Patent.

1. A person of ordinary skill in the art has relevant design experience.

As Dr. Reinhall explains, a person of ordinary skill in the art at the time of the of the '743 Patent's inventions would be (a) a person with a degree in mechanical engineering, electrical engineering, or an equivalent degree, with at least six months experience designing medical devices that include electrical components (hereafter

"e-medical devices"); or (b) a person without the foregoing engineering education, but who achieved similar knowledge through approximately five years' experience designing e-medical devices. (Ex. 2001 ¶ 31.)[2] To determine the level of ordinary skill in the art, the Board may consider factors such (i) as the educational level of the inventor and (ii) the type of problems encountered in the art. *Daiichi*, 501 F.3d at 1256.

First, the backgrounds of the '743 Patent's named inventors support Patent Owner's POSITA definition, including the requirement for at least some experience designing e-medical devices. As shown by their prior applications, inventors Jason Felix, Jon Bishay, and Gust Bardy all had several years of relevant design experience before tackling the problems addressed by the '743 Patent and conceiving of its inventions. (*See, e.g.,* Ex. 2006, U.S. Patent No. D639,437 (filed October 8, 2010); Ex. 2007, U.S. Patent No. 8,285,370 (filed October 8, 2010.) The inventors' experience designing e-medical devices supports Patent Owner's definition of a POSITA as having some experience designing e-medical devices. *See Daiichi*, 501 F.3d at 1257 (finding that the inventors all being specialists involved in the development of drug and ear treatments supported a finding that a POSITA would

[2] As noted by Dr. Reinhall, a biomedical engineering degree may be an equivalent degree depending on the coursework of the program. (Ex. 2001 ¶ 31 n.1.)

be a person engaged in developing pharmaceutical formulations, as opposed to merely a physician who has familiarity with such formulations).

Second, the problems encountered in the art are *engineering* problems that could not be addressed by someone with neither an engineering degree nor any experience designing e-medical devices. The level of ordinary skill in the art should coincide with the education, training, and experience of a person who would be capable of addressing the problems encountered in the art (albeit in non-inventive ways). *Daiichi*, 501 F.3d at 1257; *DyStar Textilfarben GmbH & Co. Deutschland KG v. C.H. Patrick Co.*, 464 F.3d 1356, 1362 (Fed. Cir. 2006).

As explained by Dr. Reinhall, the disclosures of the '743 Patent—including disclosures acknowledged by Petitioner—show that the problems encountered in the art "are engineering problems involving issues such as compressional, tensile, torsional, and shear forces; material properties; electrical power consumption; circuits; and electrical hardware architectures, and component configurations and layouts." (Ex. 2001 ¶ 33.) Consider the following:

- The '743 Patent criticizes prior art ECG monitoring devices for being arduous to employ, cumbersome, and expensive—problems that Dr. Reinhall explains go to the shapes of the devices, the layouts and configurations of components on the device, their electrical hardware

architectures, and the types of hardware components utilized. (Ex. 1001 at 1:6–2:2, 2:50–57; Ex. 2001 ¶ 34; *see also* Petition at 9.)

- The '743 Patent describes problems with prior art ECG monitoring devices lacking adequate battery capacity. (Ex. 1001 at 3:8–11.) "Lack of adequate battery capacity arises from, among other things, size constraints in the devices, hardware selection, the layout of the circuitry, sampling rate, and the amount and frequency of power being drawn from the battery by the various components that require power." (Ex. 2001 ¶ 35.) Battery capacity implicates competing design considerations regarding battery power, circuitry layout, the types and number of electrical components, and functions of electrical components. (*Id.*)
- The '743 Patent describes problems with prior art ECG monitoring devices not being adequately waterproofed, which involves whether or how the electronics are housed. (Ex. 1001 at 3:11–14; Ex. 2001 ¶ 36.)
- The '743 Patent also recognizes that "a need remains for an extended wear continuously recording ECG monitor practically capable of being worn for a long period of time in both men and women" and for integrating "wider-ranging physiological and 'life tracking'-type data into long-term ECG and physiological data monitoring." (Ex. 1001 at 1:36–42; *see also* Petition at 9–10.) According to Dr. Reinhall, "[a]ddressing those needs presents

challenging engineering problems because extending the sensing time of an ECG monitor is at odds with adding sensing and processing capabilities and memory capacity, as those functions require more, not less, energy consumption." (Ex. 2001 ¶ 37.) Moreover, adding functionalities to the device may require additional components or components of larger sizes, which would make maintaining the device on the patient for an extended period time more problematic. (*Id.*)

- Furthermore, the '743 Patent describes the problems arising from "various compressional, tensile, and torsional forces" that can dislodge electrodes—an engineering problem that is particularly complex in light of the dynamic environmental and physical conditions presented by the device being attached to skin, the characteristics and properties of which vary from patient to patient. (Ex. 1001 at 2:9–23; Ex. 2001 ¶ 38.)

The prior art also identifies technical, engineering problems related to the design and structure of relevant cardiac monitoring devices, such as the following:

- As explained by Dr. Reinhall, *Mazar* recognizes problems with the configurations, materials, and mechanical properties of the prior art devices, and the resulting challenges posed by the forces being applied to them during use, criticizing prior art devices as "bulky and uncomfortable," "cumbersome," having "excessive weight," being stiff,

and un-adhering from the patient during use. (Ex. 1003 at ¶¶ [0003]–[0004]; Ex. 2001 ¶ 39; *see also* Petition at 17.)

- *Mazar* recognizes the struggles of artisans in balancing the energy demands and constraints of the devices, describing the prior art as having problems with "energy consumption." (Ex. 1003 at ¶ [0004]; Ex. 2001 ¶ 41.)
- *Yang* identifies the problems caused by various forces affecting prior art devices during use, explaining that ECG monitoring devices "are subject to repeated use and high wear and tear." (Ex. 1005 at 1:27–37; Ex. 2001 ¶ 42; *see also* Petition at 23.)
- U.S. Patent No. 5,862,803 ("*Besson*") describes prior art cardiac monitoring devices having cables that "obstruct the patient and highly limit his or her freedom of movement" and, "due to the stiffness of the cables and the lever forces connected therewith, the cables become easily detached particularly when the patient moves." (Ex. 1008 at 1:46–52; Ex. 2001 ¶ 43.) As Dr. Reinhall explains, those issues reflect problematic device layouts and their failures to withstand the forces applied during use. (Ex. 2001 ¶¶ 34, 37–38.)

- *Besson* describes problems with battery life due to the demands on the battery from the processing, recording, and transmitting components. (Ex. 1008 at 2:44–49; Ex. 2001 ¶ 44.)
- International Publication No. WO 2008/005015 ("*Shennib*") describes the problem of prior art devices being unable to provide power for sufficient amounts of time. (Ex. 1013 at ¶ [0011]; Ex. 2001 ¶ 45.)
- *Shennib* recognizes problems with cardiac monitoring device layouts and configurations, calling them "bulky," expensive, and uncomfortable. (Ex. 1013 ¶¶ [0009]–[0010]; Ex. 2001 ¶ 46.)
- U.S. Patent No. 7,206,630 ("*Tarler*") describes a litany of drawbacks in prior art devices. As Dr. Reinhall explains, the drawbacks discussed in *Tarler* arise from problematic device layouts and configurations, material properties, and "unique power requirements," describing rigidity of the devices preventing "good electrode contact," device cumbersomeness, and problems delivering sufficient power to all desired components. (Ex. 1014 at 2:51–3:3 Ex. 2001 ¶ 47.)

As Dr. Reinhall explains in greater detail, mechanical and electrical engineers receive specific education and training in mechanics, material properties, power consumption, circuitry, and electrical hardware architectures, and they could apply that education and training to try to develop solutions to the problems encountered

in art, particularly after obtaining some experience with e-medical devices such as cardiac monitoring devices. (Ex. 2001 ¶¶ 48–54.) For example, mechanical and electrical engineers receive specific education and training on energy efficiency, how structures move when subjected to forces, manufacturing, and material science. (*Id.* ¶¶ 50–52.) This specific education and training allows them to address engineering problems by giving them the tools to identify, calculate, and reduce the effects of forces applied to structures during use, reduce unnecessary power loses, select appropriate materials, and more. (*Id.* ¶¶ 49, 52.) Without those tools, a person would not be able to address the problems encountered in the art. (*See id.* ¶¶ 53–62, 65-69.)

Thus, in order to address the problems identified by the '743 Patent and related prior art, a POSITA would need to have the technical knowledge that comes with an engineering education and experience in e-medical devices, or real-world design experience with e-medical devices that would provide similar technical know-how.

2. Medical professionals without relevant design experience are not persons of ordinary skill in the art.

While Patent Owner's and Petitioner's POSITA definitions diverge in several ways, the key issue at this stage is whether Petitioner is correct that a person with no experience designing e-medical devices such as cardiac monitoring devices can qualify as a POSITA. Petitioner is wrong.

Petitioner's definition should be rejected because it includes medical professionals and other persons with no experience whatsoever designing any type of medical device. Petitioner and Dr. Akar offer two alternate sets of POSITA qualifications: (i) an education requirement (a "bachelor's degree" from one of several medical disciplines or electrical engineering) with two to three years of "clinical experience in the field of biomedical engineering;" or (ii) several years of "medical work" with "knowledge of the electronic design and operation of cardiac monitoring technologies." (Petition at 5–6.) Even if one were to read Dr. Akar's definition as narrowly as possible, it covers persons such as Dr. Akar—who has experience using electrocardiographic devices on patients—but does not require any experience actually ***designing*** cardiac monitoring devices or any other kind of e-medical device. (Petition at 5–6; Ex. 1002 ¶ 43; Ex. 2001 ¶ 63, 67-69.)[3]

[3] Dr. Akar's definition is much broader than this narrow reading and considers individuals with no experience in the mechanical or electrical arts to be POSITAs. His definition (via its second prong) would cover essentially all cardiac nurses and cardiologists in the United States who are familiar with the general design and operation of the cardiac monitoring equipment they use in their clinics and hospitals on a daily basis. (Ex. 2001 ¶ 69.) Dr. Akar's definition would also cover (via its first prong) a person having "clinical" experience in the field of "biomedical

As discussed above in Section V, the Board is left guessing how Petitioner and Dr. Akar reached this conclusion because they provide no explanation or evidentiary support, so the Board should reject their POSITA definition. *See TQ Delta*, 942 F.3d at 1360–63; *Xerox*, 2022 WL 3648989, at *6; 37 C.F.R. § 42.65.

But, moving on to the substance of the definition, the reason Petitioner and Dr. Akar provide no support for their POSITA definition is likely because it is unsupportable. In Section VI.A.1 above, Patent Owner demonstrated why design experience is required, including because the problems encountered in the art are engineering problems involving issues such as compressional, tensile, torsional, and shear forces; material properties; electrical power consumption; circuits; and electrical hardware architectures. (*See* Section VI.A.1.) Additionally, and for the avoidance of doubt, a physician or medical worker without experience designing e-medical devices is not capable of understanding and addressing these problems, and therefore cannot qualify as a POSITA. (Ex. 2001 ¶¶ 55–69.) Such medical professionals may understand ***the need*** for ECG monitoring devices to be less bulky, more comfortable, and last longer after receiving feedback from patients or

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engineering," but "clinical experience" involves patient care, and biomedical engineering is a huge field that covers disparate technologies ranging from stem cell research to bone implants. (*Id.* ¶¶ 65–68.)

reviewing outputs from the devices, but they would not possess the knowledge, training and experience necessary ***to design*** a device that addresses these needs (e.g., to create a device's electrical hardware or architecture, to modify the size or shape of device, reduce the compressional, tensile, and torsional forces that can dislodge its electrodes, or make a device more energy efficient). (*Id.* ¶¶ 58–62, 69.)[4]

Dr. Reinhall's opinions are supported by his direct, day-to-day experience with the University of Washington's Engineering Innovation in Health Program ("Innovation in Health Program") as well as other collaborations with hospitals and medical device companies. (*Id.* ¶¶ 55–62.) In the Innovation in Health Program, Dr. Reinhall, other engineering faculty members, and his engineering students work together to develop medical devices that address the problems and needs of medical

[4] To the extent Dr. Reinhall's declaration creates factual disputes with Dr. Akar's declaration or the Petition, Petitioner ***is not*** entitled to any presumption in its favor. *See* 37 CFR § 42.108(c); 85 FR 79120 at 79120, 79122 (noting that Section 42.108(c) was revised "to eliminate the presumption that a genuine issue of material fact created by the patent owner's testimonial evidence filed with a preliminary response will be viewed in the light most favorable to the petitioner for purposes of deciding whether to institute a review"), available at https://www.govinfo.gov/content/pkg/FR-2020-12-09/pdf/2020-27048.pdf.

professionals from the University of Washington's School of Medicine and elsewhere. (*Id.* ¶ 56.) Since its founding, Dr. Reinhall has overseen over 65 medical device design projects, all of which resulted in the development of a prototype device. (*Id.* ¶¶ 12, 57.) For each of those projects, a medical professional approached the engineering department at the University of Washington to design a medical device based on an identified problem or need. (*Id.*) Without exception in Dr. Reinhall's experience, the medical professionals who lack extensive experience designing medical devices have not provided any workable design solutions because they lack the skills necessary to do so. (*Id.* ¶¶ 58–62.) Instead, the medical professionals only provide clinical and medical information and background information on the problem or need, and they turn to Dr. Reinhall, his engineering colleagues, and their engineering students for all aspects of the design of the devices. (*Id.*)

Dr. Reinhall's specific experience further illustrates the importance of an engineering education and experience in designing medical devices. In one project, Dr. Reinhall, along with another engineer, designed an improved endoscope, which is a device that is inserted into the human body and used to view body cavities and organs. (*Id.* ¶¶ 19, 60.) The project began with a need similar to those encountered in the art here: to try to make an e-medical device less bulky. (*Id.*) At the time, existing endoscopes employed many fiberoptic cables, along with other electrical

and mechanical components, so they required relatively large diameter housings that prevented endoscopes from fitting into many places. (*Id.*)

The physicians with whom Dr. Reinhall worked on that project were aware of the problems with existing endoscopes and explained that physicians needed an endoscope that was small enough to be inserted into smaller parts of the body, but they did not offer any design solutions to those problems because they lacked engineering skills. (*Id.*) The physicians—although they were knowledgeable about endoscopes through their medical practice—did not know how to reconfigure or change electrical components of an endoscope to make the endoscope thinner. (*Id.*) Dr. Reinhall and his engineering colleague were able to come up with a solution that reduced the number of fiberoptic cables in the device because Dr. Reinhall and his engineering colleague had engineering skills through their engineering education, training, and experience. (*Id.*)

For another project, an intestinal surgeon approached the Innovation in Health Program after noticing that reconnecting intestines via stitching was time consuming and sometimes resulted in inadequate connections that leaked, leading to infections. (*Id.* ¶ 59.) The surgeon asked for help developing an alternative way to reattach intestines that did not involve stitching. (*Id.*) While the surgeon understood what the human body could withstand, where risks of infections may arise, how the intestines heal over time, existing techniques and devices, and other medical and biological

information, he lacked knowledge in engineering fundamentals and the basic engineering skills that were necessary to design a device that could act as an alternative to stitches. (*Id.*) As a result, he did not provide any design solutions during the pendency of the project. (*Id.*) Meanwhile, Dr. Reinhall, other members of the engineering faculty, and engineering students under the guidance of Dr. Reinhall and the faculty members developed a prototype device that was faster, safer, and more effective than stitching. (*Id.*)

Through his experience with the Innovation in Health Program and in his collaboration with hospitals and medical device companies, Dr. Reinhall has seen firsthand that physicians are unable to come up with engineering solutions to problems identified in the art. (*Id.* ¶ 61.) Indeed, physicians' inability to address problems in the art is ***the very reason*** they approach the Innovation in Health Program in the first place. (*Id.*) Physicians need the help of engineers to develop medical devices because they lack the skills to do so themselves. (*Id.*¶ 62.) In Dr. Reinhall's experience, if a physician becomes part of the team working to develop or improve devices, their involvement is limited to providing clinical information and insight into patient preferences and treatment needs. (*See id.*)

Federal Circuit law fully supports Patent Owner's and Dr. Reinhall's POSITA definition (which requires experience designing devices) and defeats Petitioner's and Dr. Akar's definition (which covers medical practitioners who are merely

familiar with devices though clinical use). In *Daiichi*, prior art antibiotic treatments for ear infections caused damage to the ear, and the invention was a new antibiotic compound that would eliminate that problem. 501 F.3d at 1257. The parties disputed whether a POSITA would be (a) a doctor who has experience treating ear infections and possessed some pharmacological knowledge or (b) a person engaged in developing new pharmaceuticals or who has special training in pharmaceutical formulations. *Id.* at 1256. The Federal Circuit recognized that although a doctor may have knowledge about treating ear infections and prescribing medications to treat them in the course of their medical practice, doctors would not have the training or knowledge to develop new antibiotic compounds that would address the problems with existing formulations. *Id.* at 1256–57. As a result, the Federal Circuit held that the level of ordinary skill in the art would be that of a person engaged in developing pharmaceutical formulations or an ear treatment specialist who also had specialty training in pharmaceutical formulations. *Id.*; *see also DyStar*, 464 F.3d at 1362–63 (for process for dying textile materials, POSITA required knowledge of chemistry and systems engineering, not merely experience using dying processes to dye textiles).

Therefore, like in *Daiichi* and *Dystar*, the problems encountered in the art demonstrate that a POSITA must be a designer—not a mere user—of e-medical devices such as cardiac monitoring devices.

B. The Petition is Devoid of Evidence Showing Why a POSITA Would Combine the Prior Art, so Petitioner Fails to Establish Obviousness.

The POSITA definition is critical here because Petitioner's only testimony on key topics—reasons to combine prior art references—comes from Dr. Akar, who is unqualified to give credible opinions. Without his testimony, Petitioner has nothing left, and the Petition fails.

1. Dr. Akar is not qualified to give testimony from the perspective of a person of ordinary skill in the art.

The Board cannot rely on Dr. Akar's opinions on obviousness because he—a physician with no experience designing any type of e-medical device, including cardiac monitoring devices—is not qualified to testify from the perspective of a POSITA. *See Kyocera Senco Indus. Tools Inc. v. Int'l Trade Comm'n*, 22 F.4th 1369, 1376 (Fed. Cir. 2022) (abuse of discretion to allow testimony on any issue analyzed through the lens of a POSITA from a witness who lacked the experience necessary to qualify as a POSITA). The Board therefore cannot rely on his testimony on any such topics. *Avail Medsystems, Inc. v. Teladoc Health, Inc.*, No. IPR2022-00444, 2022 WL 2903454, at *10 (PTAB July 21, 2022) (denying institution upon finding Petitioner's expert unqualified to opine on all issues analyzed through the lens of a POSITA).

Dr. Akar admits that he is "a medical professional by training and profession" who has never "personally designed ECG monitoring systems from an engineering

standpoint." (Ex. 1002 ¶¶ 22, 34.) Indeed, his declaration and curriculum vitae demonstrate that he has no experience designing any type of e-medical device. (Ex. 1002 ¶¶ 4–22; Ex. 1006.)[5] Without any experience designing cardiac monitoring devices or any other type of e-medical device, Dr. Akar lacks the experience necessary to qualify as a POSITA, so his opinions regarding how or why a person of ordinary skill in the art would combine or modify prior art must be disregarded. "To offer testimony from the perspective of a skilled artisan in a patent case—like for claim construction, validity, or infringement—a witness must at least have ordinary skill in the art." *Kyocera*, 22 F.4th at 1376–77; *see also Best Med. Int'l, Inc. v. Eleckta Inc.*, 46 F.4th 1346, 1353–54 (Fed. Cir. 2022) (affirming Board's decision to discount expert after finding that POSITA would have "formal computer programming experience" and the expert did not); *Avail Medsystems*, 2022 WL

[5] Indeed, Dr. Akar is named on only one U.S. patent application, which does not disclose or claim any sort of new device or apparatus. (*See* Ex. 1006 at 11 (citing US20150023873); Ex. 2005 at 1 (abstract), 70–71 (claims).) Instead, his application concerns methods of diagnosing and treating medical conditions, namely methods of assessing whether a patient has an increased risk of developing atrial fibrillation, or the likelihood of responding to particular atrial fibrillation therapies, based on the level of imaging agent identified in the heart. (*See id.*)

2903454, at *10–11 (denying institution after refusing to give any weight to expert witness's opinions "regarding what a skilled artisan would have understood and/or derived from the disclosed technology" where the witness lacked experience in designing or engineering teleconferencing systems).

The facts here are similar to the facts in *Kyocera*. There, the definition of a POSITA required at least two years of experience "designing power nailers." *Kyocera*, 22 F.4th at 1376. The petitioner's expert had "advanced degrees in engineering and extensive experience in the design and manufacture of fastener driving tools," but he lacked experience in power nailer design. *Id.* As a result, despite his impressive qualifications, the expert did not qualify as a POSITA, so the Federal Circuit found that the administrative law judge abused his discretion in admitting testimony from the expert on any issue analyzed from the perspective of a POSITA. *Id.* at 1377–78.

Like the expert in *Kyocera* who lacked the power nailer design experience necessary to qualify as a POSITA, Dr. Akar lacks the device design experience necessary to qualify as a POSITA here. As a result, the Board cannot rely on any of his opinions that are made from the perspective of a POSITA, including his opinions as to how or why a POSITA would modify or combine *Mazar*, *Yang*, or *Oster*.

2. Petitioner cannot establish obviousness because the Petition is devoid of reason-to-combine evidence.

Both of Petitioner's unpatentability grounds fail because they assert obviousness over prior art references without providing any credible evidence that there would have been a reason to combine those references. When a patent challenger alleges that an invention claims an obvious combination of known elements from multiple prior art references, the challenger must prove that there was a "***reason to combine*** the known elements in the fashion claimed by the patent at issue." *See TriMed, Inc. v. Stryker Corp*., 608 F.3d 1333, 1341 (Fed. Cir. 2010) (citing *KSR Int'l Co. v. Teleflex Inc*., 550 U.S. 398 (2007)) (emphasis added). Whether there is a reason to combine prior art references is a question of fact, and where there is no competent evidence establishing a reason to combine, then there can be no finding of obviousness. *Kinetic Concepts, Inc. v. Smith & Nephew, Inc.,* 688 F.3d 1342, 1367 (Fed. Cir. 2012).

Because both of the Petition's grounds assert obviousness, it is critical for Petitioner to establish that a person of ordinary skill in the art—an actual POSITA, not the baseless one asserted by Petitioner—would have a reason to combine *Mazar* and *Yang* (Ground I) or *Oster* and *Yang* (Ground II) to produce the '743 Patent's claimed inventions. But its only evidence comes from the discredited testimony of Dr. Akar. For example, in Ground I, Petitioner relies exclusively on Dr. Akar to reach the following conclusions from the perspective of a POSITA:

- "[A] POSITA would understand" certain teachings in *Mazar* to be "optional," and a POSITA would recognize that "the failure to secure the printed circuit board to the backing could result in discomfort" or "introduce wear or tears in the backing." (Ex. 1002 ¶ 142.)
- That "putting the battery on the ends of the backing, rather than the middle, is a simple design choice that can be readily selected by a POSITA." (*Id.*)
- "A POSITA would readily understand that Yang's teaching to reuse elements of the patch (such as electronics) and replace other elements of the patch (such as the battery and the patch body), would improve the cost effectiveness of a disposable portion of a health monitoring device, such as that of Mazar . . . and create a product that is less wasteful." (*Id.* ¶ 143.)

(*See* Petition at 40–43.) Similarly, in Ground II, Petitioner relies exclusively on Dr. Akar to reach the following conclusions from the perspective of a POSITA:

- "[A] POSITA would understand that it is obvious to use a battery to power the wireless electronic monitoring systems such as *Oster*" because *Yang* "expressly discloses a battery 318 positioned directly on one end of the backing of the adherent patch," and "common sense dictates that the most obvious placement of the battery in *Oster* would be on one of its ends within one of its nodes, which provide the necessary space." (Ex. 1002 ¶ 197.)

- "A POSITA would readily understand that *Yang*'s teaching to reuse elements of the patch (such as the electronics) and replace other elements of the patch (such as the battery and the patch body), would improve the cost effectiveness of a disposable portion of a health monitoring device, such as that of *Oster* . . . ." (*Id*. at ¶ 198.)
- "Placing a battery as taught by *Yang* into one of the ends of the *Oster* patch would be a simple matter of packing well-understood components, which would be a routine and predictable for a POSITA." (*Id*.)

(*See* Petition at 65–68.) Each of those argument-critical opinions are supposedly made (as they must be) from the perspective of a POSITA, but the Board cannot rely on them because of Dr. Akar's lack of qualifications. *See Kyocera*, 22 F.4th at 1377–78.

Consequently, because obviousness requires a showing of a reason to combine by a POSITA, and because Petitioner's only reason-to-combine evidence comes from a non-POSITA incapable of giving credible testimony, Petitioner cannot establish obviousness. As a result, the Petition fails to demonstrate a reasonable likelihood of success. The Board should therefore deny institution.

VII. CONCLUSION

For the foregoing reasons, the Board should decline to institute *inter partes* review of the '743 Patent.

Date: April 24, 2023

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CERTIFICATE OF WORD COUNT

I hereby certify that the Patent Owner Preliminary Response contains 10,362 words, excluding the words in the table of contents, exhibit list, this certificate of word count, and the certificate of service.

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I hereby certify on April 24, 2023, that a true and correct copy of Patent Owner's Preliminary Response and Exhibits 2001–2007 were served in their entirety via e-mail to:

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